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Attorneys for Defendants,
Lupin Limited and Lupin Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC.,	**Civil Action No. 07-2896 (GEB) (JJH)**
Plaintiffs,	***Document Electronically Filed***
v.	
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	
Defendants.	

DEFENDANTS' ANSWER AND COUNTERCLAIM

Defendants, Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin"), by their attorneys, respond to the averments made in the numbered paragraphs of the complaint filed by Plaintiffs, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"), as follows:

Complaint Paragraph 1: Teva Ltd. is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

Answer: Lupin admits the allegations in paragraph 1.

Complaint Paragraph 2: Teva USA is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is a wholly-owned subsidiary of Teva Ltd.

Answer: Lupin admits the allegations in paragraph 2.

Complaint Paragraph 3: On information and belief, Defendant Lupin Limited is an Indian corporation based in Mumbai, India. On further information and belief, Defendant Lupin Limited is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey.

Answer: With respect to paragraph 3 of the complaint, Lupin admits only that Lupin Limited is an Indian corporation based in Mumbai, India and that Lupin Limited is engaged in the business of developing, manufacturing, and selling various pharmaceutical products. Lupin denies the remaining allegations in paragraph 3.

Complaint Paragraph 4: On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a Virginia corporation with its principal place of business at Harborplace Tower, 111 South Calvert St., 21st Floor, Baltimore, MD 21202. On further information and belief, Defendant Lupin Pharmaceuticals, Inc. is registered to do business in New Jersey and maintains

a registered agent in New Jersey. On further information and belief, Defendant Lupin Pharmaceuticals, Inc. is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey.

Answer: With respect to paragraph 4 of the complaint, Lupin admits the allegations in the first and second sentences. As for the allegations in the third sentence, Lupin admits only that Lupin Pharmaceuticals, Inc. sells pharmaceutical products. Lupin denies the remaining allegations in paragraph 4.

Complaint Paragraph 5: This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and seeking injunctive relief under 35 U.S.C. §§ 281-283.

Answer: With respect to paragraph 5, Lupin admits that Teva purports to bring this action under Title 35, United States Code, to obtain injunctive relief. Lupin denies the remaining allegations in paragraph 5, and expressly denies any infringement and that Teva is entitled to any relief.

Complaint Paragraph 6: This court has subject matter jurisdiction over this controversy under 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Answer: With respect to paragraph 6 of the complaint, Lupin admits only that Teva purports to base jurisdiction on 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Complaint Paragraph 7: This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction.

Answer: Lupin admits the allegations in paragraph 7.

Complaint Paragraph 8: This Court has personal jurisdiction over Defendants because of, *inter alia*, Defendants' systematic, purposeful and continuous contacts in the District, Defendant Lupin Pharmaceuticals, Inc.'s registration in the District, and Defendant Lupin Limited's availment of the privilege of doing business in this District through its subsidiary and agent Defendant Lupin Pharmaceuticals, Inc.

Answer: Lupin denies the allegations in paragraph 8, but Lupin Limited and Lupin Pharmaceuticals, Inc. will not contest personal jurisdiction in New Jersey for the limited purposes of this action.

Complaint Paragraph 9: Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b), (c), and (d).

Answer: Lupin denies the allegations in paragraph 9, but Lupin will not contest venue in this judicial district for the limited purposes of this action.

Complaint Paragraph 10: Teva Ltd. is the owner of all right, title and interest in United States Patent Nos. 6,699,997 ("the '997 Patent"), 6,710,184 ("the '184 Patent"), 7,056,942 ("the '942 Patent"), and 7,126,008 ("the '008 Patent"; collectively, "the patents in suit") relating to, *inter alia*, various forms of a chemical compound known as carvedilol and processes for preparing various forms of carvedilol. One polymorphic form of carvedilol is known as "Form II."

Answer: With respect to paragraph 10 of the complaint, the allegations therein are unclear and nonspecific and Lupin cannot fairly respond to same in their present form, but insofar as Lupin understands the allegations, without waiver of the foregoing, Lupin denies the allegations in paragraph 10, but avers that (a) Teva Pharmaceutical Industries Ltd. is listed as the

assignee of all of the patents in suit; (b) the title of the '997 patent is "Carvedilol"; (c) the title of the '184 patent is "Crystalline Solids of Carvedilol and Processes for Their Preparation"; (d) the title of the '942 patent is "Carvedilol"; (e) the title of the '008 patent is "Carvedilol"; and (f) a crystalline form of carvedilol has been called "Form II."

Complaint Paragraph 11: The '997 Patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on March 2, 2004 for an invention entitled "Carvedilol." A copy of the '997 Patent is attached as Exhibit A.

Answer: With respect to paragraph 11 of the complaint, Lupin admits only that what appears to be a copy of the '997 patent is attached as Exhibit A to the complaint and the face of the '997 patent speaks for itself. Lupin specifically denies that the PTO duly and legally issued the '997 patent, and denies any remaining allegations in paragraph 11.

Complaint Paragraph 12: The '008 Patent was duly and legally issued by the PTO on October 24, 2006 for an invention entitled "Carvedilol." A copy of the '008 Patent is attached as Exhibit B.

Answer: With respect to paragraph 12 of the complaint, Lupin admits only that what appears to be a copy of the '008 patent is attached as Exhibit B to the complaint and the face of the '008 patent speaks for itself. Lupin specifically denies that the PTO duly and legally issued the '008 patent, and denies any remaining allegations in paragraph 12.

Complaint Paragraph 13: The '997 and the '008 Patents claim processes for preparing carvedilol.

Answer: With respect to paragraph 13 of the complaint, the allegations therein are unclear and nonspecific and Lupin cannot fairly respond to same in their present form, but insofar as Lupin understand the allegations, without waiver of the foregoing, Lupin avers that

claim 1 of the '997 patent concerns a process for making carvedilol and that claim 1 of the '008 patent concerns a process for making carvedilol, and denies the remaining allegations in paragraph 13.

Complaint Paragraph 14: The '184 Patent was duly and legally issued by the PTO on March 23, 2004 for an invention entitled "Crystalline Solids of Carvedilol and Processes for Their Preparation." A copy of the '184 Patent is attached as Exhibit C.

Answer: With respect to paragraph 14 of the complaint, Lupin admits only that what appears to be a copy of the '184 patent is attached as Exhibit C to the complaint and the face of the '184 patent speaks for itself. Lupin specifically denies that the PTO duly and legally issued the '184 patent, and denies any remaining allegations in paragraph 14.

Complaint Paragraph 15: The '184 Patent claims processes for preparing carvedilol Form II.

Answer: With respect to paragraph 15 of the complaint, the allegations therein are unclear and nonspecific and Lupin cannot fairly respond to same in their present form but insofar as Lupin understand the allegations, without waiver of the foregoing, Lupin avers that claim 1 of the '184 patent concerns a process for making carvedilol Form II, and denies the remaining allegations in paragraph 15.

Complaint Paragraph 16: The '942 Patent was duly and legally issued by the PTO on June 6, 2006 for an invention entitled "Carvedilol." A copy of the '942 Patent is attached as Exhibit D.

Answer: With respect to paragraph 16 of the complaint, Lupin admits only that what appears to be a copy of the '942 patent is attached as Exhibit D to the complaint and the face of

the '942 patent speaks for itself. Lupin specifically denies that the PTO duly and legally issued the '942 patent, and denies any remaining allegations in paragraph 16.

Complaint Paragraph 17: The '942 Patent claims, *inter alia*, a hydrate form of carvedilol hydrochloride.

Answer: With respect to paragraph 17 of the complaint, the allegations therein are unclear and nonspecific and Lupin cannot fairly respond to same in their present form but insofar as Lupin understand the allegations, without waiver of the foregoing, Lupin avers that claim 1 of the '942 patent concerns carvedilol hydrochloride hydrate, and denies the remaining allegations in paragraph 17.

Complaint Paragraph 18: Carvedilol is a pharmaceutical compound useful in the treatment of congestive heart failure. It is the active pharmaceutical ingredient ("API") in the product sold by GlaxoSmithKine ("GSK") under the trade name COREG®. COREG® is included in the United States Food and Drug Administration's ("FDA") list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book."

Answer: Lupin admits the allegations in paragraph 18.

Complaint Paragraph 19: The carvedilol compound is disclosed and claimed in U.S. Patent No. 4,503,067 ("the '067 Patent"), which is owned by GSK. The '067 Patent is listed in the FDA's Orange Book in association with COREG®. The '067 Patent expired on March 5, 2007.

Answer: With respect to paragraph 19 of the complaint, the allegations therein are unclear and nonspecific and Lupin cannot fairly respond to same in their present form but insofar as Lupin understand the allegations, without waiver of the foregoing, Lupin admits only that (a) the '067 patent is listed in the Orange Book in association with COREG®; and (b) the

'067 patent expired on March 5, 2007. Lupin denies the remaining allegations in paragraph 19, but avers that claim 8 of the '067 patent concerns carvedilol.

Complaint Paragraph 20: Pursuant 21 U.S.C. § 355a, GlaxoSmithKline was awarded a six-month period of pediatric exclusivity following the expiration of the '067 Patent. GlaxoSmithKline's pediatric exclusivity period extends from March 5, 2007 to September 5, 2007. Pursuant to this exclusivity, the FDA cannot grant final approval to any Abbreviated New Drug Application ("ANDA") holders for carvedilol during that period. The FDA may grant final approval to ANDA holders beginning immediately upon expiration of GSK's pediatric exclusivity period.

Answer: With respect to paragraph 20 of the complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 20, and therefore denies them, but avers that the Orange Book indicates that the '067 patent received a six-month period of pediatric exclusivity and that this exclusivity expires on September 5, 2007.

Complaint Paragraph 21: There are nine holders of ANDAs for carvedilol that have received tentative approval from the FDA. Final approval is expected to be granted to these ANDA holders shortly after the expiration of GSK's pediatric exclusivity period on September 5, 2007. Once each ANDA holder receives final approval, it may market carvedilol tablets in the United States.

Answer: With respect to paragraph 21 of the complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 21, and therefore denies them, but avers that as of the date of this answer, the Orange Book lists

nine holders of ANDAs for carvedilol that have received tentative approval from the FDA, and that once an ANDA receives final approval, the ANDA holder may market its ANDA product.

Complaint Paragraph 22: Under the Act, ANDA holders must provide detailed information to the FDA about how the API to be used in their proposed generic products will be made. ANDA holders may purchase API from a supplier instead of making API themselves. Suppliers of API typically are reluctant to disclose confidential information about their manufacturing processes to their customers and, instead, may submit this confidential information directly to the FDA in the form of a Drug Master File ("DMF"). ANDA filers who intend to purchase API from a given supplier may then reference the API supplier's DMF in their ANDAs. Upon receiving an ANDA referencing a DMF, the FDA will separately review the DMF as part of the ANDA approval process. Accordingly, the act of filing a DMF indicates that the present intent of the DMF filer is to supply API in the United States.

Answer: With respect to paragraph 22 of the complaint, Lupin admits that ANDA holders must provide certain information regarding the API to the FDA and that this information may be contained in a DMF. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 22, and therefore denies them.

Complaint Paragraph 23: On information and belief, Defendants have filed DMF No. 19218 for carvedilol API with the FDA.

Answer: Lupin admits the allegations in paragraph 23.

Complaint Paragraph 24: On information and belief, Defendants plan and intend to supply carvedilol API to one or more third party ANDA holder(s), with the knowledge and intent that the third party ANDA holder(s) will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic carvedilol tablets in the United States.

Answer: Lupin denies the allegations in paragraph 24.

Complaint Paragraph 25: On information and belief, Defendants plan and intend to supply carvedilol API to the third party ANDA holder(s) with the knowledge and intent that the third party ANDA holder(s) will engage in the activities described in paragraph 24 immediately upon receiving final approval of the ANDA(s) from the FDA, and that said approval will occur shortly after GSK's pediatric exclusivity period expires on September 5, 2007.

Answer: Lupin denies the allegations in paragraph 25.

Complaint Paragraph 26: On information and belief, Defendants plan and intend to supply carvedilol API to the third party ANDA holder(s) with the knowledge and intent that the third party ANDA holder(s) will engage in the activities described in paragraph 24 prior to the expiration of the patents in suit.

Answer: Lupin denies the allegations in paragraph 26.

Complaint Paragraph 27: On information and belief, Defendants plan and intend to import carvedilol API into the United States for sale to third party ANDA holder(s).

Answer: Lupin denies the allegations in paragraph 27.

Complaint Paragraph 28: On information and belief, Defendants' carvedilol API infringes or will infringe one or more claims of the patents in suit, and/or is or will be made by a process that infringes one or more claims of the patents in suit. Accordingly, Defendants' plans and intentions to import and sell carvedilol API in the United States constitute imminent, threatened acts of infringement under 35 U.S.C. § 271, which give rise to an actual controversy over which the Court may exercise jurisdiction.

Answer: Lupin denies the allegations in paragraph 28.

Complaint Paragraph 29: On information and belief, Defendants' plans and intentions to supply carvedilol API to third party ANDA holders(s) outside of the United States for incorporation into products that it knows will be imported in the United States constitutes imminent, threatened inducement of infringement under 35 U.S.C. § 271, which gives rise to an actual controversy over which this Court may exercise jurisdiction.

Answer: Lupin denies the allegations in paragraph 29.

Complaint Paragraph 30: Plaintiffs have made a reasonable effort to determine the chemical composition of Defendants' carvedilol API, as well as the processes by which Defendants' carvedilol API is or will be made. On May 8, 2007, Teva USA notified Defendants of the existence of the patents in suit and sought information allowing Plaintiffs to ascertain whether Defendants' API falls within the scope of one or more of the patents in suit, and/or whether Defendants' API is made pursuant to a process that falls within the scope of one or more of the patents in suit. In particular, Teva USA requested samples of all carvedilol API made pursuant to Defendants' DMF, and a detailed description of all processes that will be used to manufacture Defendants' carvedilol API. Teva USA offered to enter into a confidentiality agreement to protect the confidentiality of any information disclosed by Defendants. Pursuant to this offer, Teva USA supplied a proposed confidentiality agreement to Defendants.

Answer: Lupin denies the allegations in paragraph 30, but avers that Teva sent a letter dated May 8, 2007 to Lupin mentioning the patents in suit and requesting process information and samples.

Complaint Paragraph 31: Defendants have not provided to Teva USA samples of Defendants' carvedilol API or the detailed information requested regarding the processes by

which Defendants' carvedilol API is made, despite Teva USA's offer of confidentiality. Further, Plaintiffs have been unable to obtain samples of Defendants' API from a public source.

Answer: Lupin denies the allegations in paragraph 31, but avers that it did not respond to Teva's letter and did not provide process information or samples to Teva.

Complaint Paragraph 32: Without the requested information, Plaintiffs are unable to determine whether Defendants' API infringes one or more compounds claimed in the patents in suit, or whether the processes by which Defendants' API is made infringe one or more methods claimed in the patents in suit. For this reason, Plaintiffs cannot conclusively determine whether Defendants infringe each of the patents in suit unless and until Defendants provide samples of their API and disclose to Plaintiffs the processes by which the API is made.

Answer: Lupin denies the allegations in paragraph 32.

Complaint Paragraph 33: In the absence of a sufficient response from Defendants, Plaintiffs have no choice but to resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, the information required to confirm their beliefs as to infringement and to present the Court evidence that Defendants will infringe the patents in suit.

Answer: Lupin denies the allegations in paragraph 33.

Complaint paragraph 34: As a direct and proximate consequence of the planned and intended infringement by Defendants, Plaintiffs will be injured in their business and property rights unless the infringement is enjoined by the Court, and will suffer injury for which they are entitled to relief.

Answer: Lupin denies the allegations in paragraph 34.

COUNT I

Declaratory Judgment of Patent Infringement

Complaint Paragraph 35: Plaintiffs repeat and reallege Paragraphs 1 to 34 of the Complaint as if fully set forth herein.

Answer: Lupin's answers to the allegations in paragraphs 1 to 34 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 36: On information and belief, the importation, manufacture, use, sale and/or offer for sale by Defendants of their carvedilol API pursuant to DMF No. 19218 will infringe, either literally or under the doctrine of equivalents, one or more claims of the '997, '184, '942, and/or '008 Patents, or will contribute to or induce such infringement, under 35 U.S.C. § 271.

Answer: Lupin denies the allegations in paragraph 36.

SEPARATE DEFENSES

Without any admission as to the burden of proof or as to any of the averments in the complaint, Lupin sets forth the following defenses:

First Defense

The '997, '184, '942, and '008 patents' claims do not, either literally or under the doctrine of equivalents, cover Lupin's carvedilol API, the process used to make Lupin's carvedilol API, or any process according to DMF No. 19218. Thus, Lupin has not infringed and will not infringe any of the '997, '184, '942, and '008 patents by making, using, selling, offering for sale, marketing, or importing carvedilol API according to DMF No. 19218.

Second Defense

The '997, '184, '942, and '008 patents and all their claims are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

COUNTERCLAIM

Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin") by way of counterclaim against Plaintiffs, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"), state:

The Parties

1. Lupin Pharmaceuticals, Inc. is a Virginia corporation with its principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

2. Lupin Limited is an Indian corporation with an address at Laxmi Towers, B Wing, Bandra Kurla Complex, Mumbai, 400 051, India.

3. On information and belief, Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

4. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is a wholly owned subsidiary of Teva Ltd.

Jurisdiction

5. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Lupin seeks declaratory relief, *i.e.*, a declaration that the patents in suit are not infringed and that they are invalid.

6. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Factual Background

7. United States Patent No. 6,699,997 ("the '997 patent"), entitled "Carvedilol," was issued on March 2, 2004.

8. United States Patent No. 6,710,184 ("the '184 patent"), entitled "Crystalline Solids of Carvedilol and Processes for Their Preparation," was issued on March 23, 2004.

9. United States Patent No. 7,056,942 ("the '942 patent"), entitled "Carvedilol," was issued on June 6, 2006.

10. United States Patent No. 7,126,008 ("the '008 patent"), entitled "Carvedilol," was issued on October 24, 2006.

11. Upon information and belief, the '997 patent, the '184 patent, the '942 patent, and the '008 patent, collectively "the patents in suit," are all assigned to Teva Pharmaceutical Industries Ltd.

12. The patents in suit concern various processes of preparing various forms of carvedilol, including a polymorphic form known as "Form II," and a hydrate form of carvedilol hydrochloride.

13. Lupin submitted DMF No. 19218 for carvedilol API to the Food and Drug Administration ("FDA").

14. Lupin's DMF includes confidential information concerning Lupin's process for making carvedilol API.

FIRST COUNT
(Declaration of Noninfringement)

15. Lupin repeats and realleges paragraphs 1 through 14 of the counterclaim.

16. Teva has asserted the '997, '184, '942, and '008 patents against Lupin. Teva maintains—and Lupin denies—that the '997, '184, '942, and '008 patents' claims cover Lupin's carvedilol API and/or the process used to make Lupin's carvedilol API.

17. The '997, '184, '942, and '008 patents' claims do not, either literally or under the doctrine of equivalents, cover Lupin's carvedilol API , the process used to make Lupin's

carvedilol API, or any process according to DMF No. 19218. Thus, Lupin has not infringed and will not infringe any of the '997, '184, '942, and '008 patents by making, using, selling, offering for sale, marketing, or importing carvedilol API according to DMF No. 19218.

18. Lupin and Teva have adverse legal interests, and there is a substantial controversy between Lupin and Teva of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the noninfringement of the '997, '184, '942, and '008 patents.

19. Lupin is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of Lupin's carvedilol API does not infringe any of the '997, '184, '942, and '008 patents and that the process used to make Lupin's carvedilol API does not infringe any of the patents in suit.

SECOND COUNT
(Declaration of Invalidity)

20. Lupin repeats and realleges paragraphs 1 through 14 of the counterclaim.

21. The '997, '184, '942, and '008 patents and all their claims are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

22. Teva maintains—and Lupin denies—that the '997, '184, '942, and '008 patents are valid.

23. Lupin and Teva have adverse legal interests, and there is a substantial controversy between Lupin and Teva of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '997, '184, '942, and '008 patents.

24. Lupin is entitled to a judicial declaration that the '997, '184, '942, and '008 patents are invalid.

WHEREFORE, Lupin demands judgment in its favor and against Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. as follows:

(a) Dismissing the complaint with prejudice and denying each request for relief made by Teva Pharmaceutical Industries Ltd. or Teva Pharmaceuticals USA, Inc.;

(b) Declaring the '997 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Lupin's carvedilol API and not infringed by any process used to make Lupin's carvedilol API;

(c) Declaring the '184 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Lupin's carvedilol API and not infringed by any process used to make Lupin's carvedilol API;

(d) Declaring the '942 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Lupin's carvedilol API and not infringed by any process used to make Lupin's carvedilol API;

(e) Declaring the '008 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Lupin's carvedilol API and not infringed by any process used to make Lupin's carvedilol API;

(f) Declaring the '997 patent and all its claims invalid;

(g) Declaring the '184 patent and all its claims invalid;

(h) Declaring the '942 patent and all its claims invalid;

(i) Declaring the '008 patent and all its claims invalid;

(j) Enjoining Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc., their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with any plaintiff from threatening to assert or otherwise attempting to enforce any of the '997, '184, '942, and '008 patents against Lupin, its customers, suppliers, or anyone in privity with Lupin;

(k) Adjudging this to be an exceptional case under 35 U.S.C. § 285 and awarding Lupin its attorney fees;

(l) Awarding Lupin its costs and expenses; and

(m) Awarding Lupin such other and further relief as the Court deems just and proper.

Respectfully submitted,

SAIBER SCHLESINGER SATZ & GOLDSTEIN, LLC

Attorneys for Defendants,
Lupin Limited and Lupin Pharmaceuticals, Inc.

Dated: July 31, 2007

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

In accordance with Local Civil Rule 11.2, I certify that the within matter is not the subject of any pending or contemplated court, arbitration or administrative proceeding, and that there are no other parties who ought to be joined in this action.

SAIBER SCHLESINGER SATZ & GOLDSTEIN, LLC

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CERTIFICATION OF NON-ARBITRATILITY AND NON-MEDIATION

In accordance with Local Civil Rule 201.1(d)(1), I certify that the within matter is not subject to compulsory arbitration or to mediation because this action seeks injunctive relief.

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